

Claims

1. A method for the production of amphiphile particles having incorporated therein at least one active agent, said method comprising forming a dispersion of particles comprising at least one amphiphilic structuring agent in a solution of at least one active agent, heating said dispersion to an elevated temperature, followed by cooling to around ambient temperature.
2. A method as claimed in claim 1 wherein said heating is to a temperature and for a period sufficient to provide, after cooling, an incorporation of active agent into said particles which is at least 130% of the maximum incorporation provided by equilibrating said particles in a solution of at least one active agent at 37°C for up to 3 days.
3. A method for increasing the incorporation of at least one active agent into amphiphile particles, above the level achievable by equilibration at 37°C, said method comprising forming a dispersion of particles comprising at least one amphiphilic structuring agent in a solution containing an excess of at least one active agent and heating said dispersion to an elevated temperature, followed by cooling, preferably to around ambient temperature.
4. A method as claimed in any of claims 1 to 3 wherein said particles are colloidal.
5. A method as claimed in any of claims 1 to 4 wherein said heating is to a temperature in the range 75°C to 200°C.

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6. A method as claimed in any of claims 1 to 5 wherein said heating is for a period of between 1 minute and 4 hours.

7. A method as claimed in any of claims 1 to 6 wherein, prior to loading, at least 75% by volume of said particles are of non-lamellar or micellar phase.

8. A method as claimed in any of claims 1 to 7 wherein, after loading, at least 75% by volume of said particles are of non-lamellar or micellar phase.

9. A method as claimed in any of claims 1 to 8 wherein, before loading, the equilibrium form of the particles is non-lamellar or micellar.

10. A method as claimed in any of claims 1 to 9 additionally comprising drying the amphiphile particles having incorporated therein at least one active agent.

11. Amphiphile particles, having incorporated therein at least one active agent, formed by the method of any of claims 1 to 10.

12. Amphiphile particles comprising at least one structure forming amphiphile and an active agent, wherein the incorporation of said active agent into said particles is at least 130% of the maximum incorporation provided by incubating equivalent particles not comprising any active agent in a solution of an excess of said active agent at 37°C.

13. Amphiphile particles as claimed in claim 11 or claim 12 wherein said structure forming amphiphile is one or more amphiphiles selected from natural lipids,

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synthetic lipids, surfactants, and amphiphilic copolymers.

14. Amphiphile particles as claimed in any of claims 11 to 13 wherein a portion of said structure forming amphiphile is a fatty acid and/or an oily amphiphile.

15. Amphiphile particles as claimed in any of claims 11 to 14 wherein said particles are colloidal.

16. Amphiphile particles as claimed in any of claims 11 to 15 wherein the particles are at least 75% by volume non-lamellar or micellar particles or mixtures thereof.

17. Amphiphile particles as claimed in any of claims 11 to 16 additionally comprising at least one fragmenting agent.

18. Amphiphile particles as claimed in claim 17 wherein said fragmenting agent is a surfactant with a hydrophilic lipophilic balance of at least 12.

19. Amphiphile particles as claimed in any of claims 11 to 18 wherein said particles are stable to the loss of said active agent for at least 24 hours at 25°C.

20. Amphiphile particles as claimed in any of claims 11 to 19 wherein said particles are stable in terms of particle size for at least 24 hours at 25°C.

21. A pharmaceutical composition comprising amphiphile particles as claimed in any of claims 11 to

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20 and at least one pharmaceutically tollerable carrier or excipient.

22. -A powder comprising particles as claimed in any of claims 11 to 20, optionally with some or all of the water therein removed.

23. A gel of cream comprising particles as claimed in any of claims 11 to 20, optionally with some or all of the water therein removed.